Metered administration of a therapeutic gas

Field of Invention

The invention relates to a method and to a device for the metered administration of a therapeutically effective gas to a patient, comprising a purging step for purposes of removing harmful substances from parts of the gas-carrying system.

Background of Invention

Nowadays, nitric oxide, NO, has become known as a medication against pulmonary hypertension, in other words, as a vasodilator. The advantage of treatment with the widely described NO mixtures is that NO only acts locally, that is to say, in the pulmonary circulation system, and not systemically. The NO gas mixture is administered to patients through inhalation. This means that other gas components, especially air, oxygen or other gases containing oxygen, are admixed to the therapeutically effective gas by means of various techniques.

For ventilated patients, European patent application EP 621 051 A2 discloses the procedure of metering in the nitrogen oxide mixture so that it is proportional to the volumetric flow rate, in other words, as a function of the inspiratory, inhaled flow of the air-oxygen mixture. The flow of the NO mixture can also be metered in so that it corresponds to the inhaled volume.

U.S. Pat. No. 5,839,433 or world patent WO 98/31282 discloses additional techniques for the administration of NO to a patient. These publications describe the so-called spike, peak or pulse techniques. For this purpose, a valve is usually opened for a certain period of time and then closed again during the inspiratory phase in order to dispense a certain volume of NO to the lungs of the patient. This technique is normally – although not exclusively – employed for spontaneously breathing patients, that is to say, for patients who are not hooked up to a ventilator.

Irrespective of which method is chosen for the dosing of NO, there is always a negative side effect associated with NO treatment, namely, the fact that NO is converted into NO_2 over the course of time when NO is mixed together with a gas that contains oxygen. Since air consists of approximately 21% oxygen, this phenomenon also occurs in air. If more time passes during which NO is present in the air or in oxygen, then more NO_2 is formed. For instance, more NO_2 is generated when the NO therapy is started, interrupted or resumed – since there is more time for oxidation. In other words, this is the case whenever time is available for further oxidation and whenever air and NO are present in the feed tubes and in the areas between the individual devices or else in the patient connector, which can be, for instance, a nosepiece or a mask. During such pauses, there is usually still NO in the lines and it can then react to form NO_2. Then, as a rule, the gas present in the system contains a relatively large amount of NO_2 which either has to be purged or else it reaches the patient. Since harmful effects already occur at minute concentrations, even the smallest amounts of NO_2 should not be tolerated. This problem occurs particularly often – although not exclusively – in the case of spontaneously breathing patients whereby, for example, nosepieces or masks that do not fit well fail to trigger the desired action, namely, the dosing of NO mixtures. As a result, the mixture remains in the feed line and then reacts in the presence of oxygen to form NO_2. But also due to some other erroneous detection by the sensor which triggers the start of the inspiration and thus the NO pulse to the patient, or else due to other events that prevent the initiation of the next gas mixture pulse or pulses, the NO mixture present in the feed line together with air/oxygen can lead to an elevated formation of NO_2. As a result, after a renewed triggering, the patient receives gas that has an elevated content of NO_2.

In order to eliminate this drawback, U.S. Pat. Nos. 6,125,846 and U.S. 6,109,260 each disclose a device and a method comprising a purging process. This purging process is done in such a way that, whenever there is a prolonged pause in the administration or else an apnea pause, the NO_2 mixture is purged by a prolonged continuous volumetric flow of the treatment gas, namely, NO, in

order to purge the NO_2 mixture. A disadvantage of this approach is that the purging gas itself contains NO so that it can once again react to form NO_2 during the next pause. In the worse-case scenario, the patient then once again inhales NO_2.

Summary of Invention

Consequently, it is the objective of the invention to improve these methods in such a way that they become safer and the patient is more reliably protected against inhaling NO_2 or other harmful gases.

This objective is achieved according to the invention by means of a method that involves a purging step with another gas and/or an evacuation step.

According to a first embodiment of the invention, the gas having the elevated NO_2 concentration is not purged out of the system by means of the therapeutic gas containing NO but rather with another gas, especially air, oxygen, nitrogen or other noble gases or mixtures – all of these gases are administered to the patient or else used exclusively for purging purposes. The purging process is the same as that of the state of the art cited, but the purging media are different. Other therapeutically effective gases can also be employed for the purging.

According to a second, independent embodiment of the invention, the gas mixture contaminated with the harmful gas is evacuated from the system by means of a pump so that it can no longer reach the patient.

The therapeutically effective gas is, for instance, NO. The mechanism by which it reacts to form NO_2 when it comes into contact with oxygen was already described above. CO constitutes another therapeutically effective gas. This gas can likewise accumulate in the lines during the dosing, as a result of which it might be administered to the patient in undesired high concentrations. Consequently, in the therapy with CO, such a purging step with another gas or an evacuation step can also be advantageous. Examples of other therapeutically

effective gases are CO_2 mixtures used to stimulate breathing, H_2 mixtures, N_2O mixtures, SF_6 mixtures, nitrosoethanol, anesthetic gases (such as, for instance, isoflurane and other volatile anesthetic gases, xenon) in order, for example, to terminate the patient's anesthesia.

Therefore, if one of the cases described occurs (sensor no longer detects breathing and does not dispense the dose, a longer interruption of the NO administration starts or ends, or else an NO monitor indicates an elevated NO_2 content), the mixture with elevated NO_2 is completely purged out of the system all the way to the patient, in other words, from the gas tank to the nosepiece, if possible. The gas elements inside the devices such as tubes and valves should also be freed of NO_2 or of the other harmful gas to the greatest extent possible. All dead spaces, feed lines or valves should be purged.

To the greatest extent possible, the evacuation should encompass all of the line parts that come into contact with the gas (nosepiece, mask, tubing, valves, tube lines, sensors, dead spaces).

The purging or evacuation can be time-controlled, sensor-controlled or event-controlled (for instance, the event that the feed of therapeutic gas to the patient is switched off – that is to say, discontinuation of the dosing). Time-controlled means that the purging or evacuation step is carried out for a certain, preset period of time and/or according to a certain time sequence. Sensor-controlled means that the purging or evacuation step is carried out as a function of a measured concentration and/or a measured throughput rate and/or a measured pressure. Particularly during the evacuation, it is recommended that the evacuation be performed to a desired residual pressure in order to ensure that most of the harmful gas is removed.

Brief Description of Drawings

Twelve embodiments of the invention will be explained in greater detail with reference to 14 Figures.

The following is shown:

Figures 1 to 6 and 13: each depicting a device to carry out a purging operation according to the invention, and

Figures 7 to 12 and 14: each depicting a device to carry out an evacuation operation according to the invention.

Detailed Description

Figure 1 shows a conventional first gas line **L1**, leading from a first gas tank **1** containing a therapeutic gas, for instance, NO (usually dissolved in nitrogen), to a patient (arrow). The line **L1** is fitted with a pressure gauge **2**, a flowmeter **4** and a valve **6** for purposes of regulating and controlling the throughput rate. **L1** can also be configured without a pressure gauge or flowmeter, or these elements can also be installed at different places, for example, downstream from the control or regulating valve. According to the invention, a second gas line **L2** is provided by means of which another gas, namely, the purging gas – here in the example oxygen from the purging gas tank **3** – can be flushed through the lines all the way to the patient. This line **L2** is likewise fitted with a pressure gauge **2**, a flowmeter **4** and a valve **6**, this time for the oxygen. The joining of **L1** and **L2** is only to be understood by way of an example and not as a requirement.

The function of the device according to the invention is as follows: only line **L1** is needed in order to treat a patient with NO. It is through this line that pulse-controlled, sensor-controlled, volume-controlled, volumetric flow rate-controlled or time-controlled NO is administered to the patient in the desired dose or quantity. If a pause in the treatment occurs, or in another event due to which the NO_2 content in the line rises, a purging step can be carried out by closing the NO valve **6** of line **L1** and opening the O_2 valve **6** of line **L2**. in this manner, O_2

is flushed through the lines all the way to the patient, thus purging the gas containing NO_2 or NO that is present in the lines.

Figure 2 shows another embodiment of the invention in which the same parts as Figure 1 are given the same reference numerals. The difference here is that now, near the therapeutic gas tank **1**, there is a shut-off valve **12** that additionally has a line **16** leading to the outside. Likewise in Figure 2, a second shut-off valve **14** is provided which likewise has a line **16** leading to the outside. Possible versions of Figure 2 are those with either only valve **12** or only with valve **14** or else with both valves. The shared feature in these two configurations is that the valve **12** or the valve **14** can each open a line **16** leading towards the outside atmosphere. In this manner, it is possible to purge directly to the tank **1**. The valve **12**, for example, for the purging step, can be switched in such a way that it is closed with respect to the therapeutic gas tank **1** and open with respect to line **16**. The gas coming from the purging line **L2** then flows through line **L1** all the way to the valve **12** and from there to the outside. If the valve **14** is also provided, then the purging gas can go from there all the way to the patient or else it can be carried through line **16** to the outside before reaching the patient. In this manner, undesired gas mixtures can already be purged before reaching the patient, and it is also possible to switch between the patient and the outside.

Figure 3 shows another embodiment in which the purging line **L2** is arranged directly before the therapeutic gas tank **1**, namely, at the valve **12**. Optionally – and consequently indicated by a broken line – a second line can be provided with a valve **6** leading to the patient (arrow). Via this line, the patient can be supplied with a second therapeutic gas from the tank **3**. This can be any desired therapeutic gas that brings about an effect that differs from that of the other therapeutic gas. It can also be useful to administer a gas containing oxygen, such as O_2 in the tank **3**, or such as air or another mixture containing oxygen. This gas can then be employed to ventilate the patient and, in a second step, for purging purposes. In order to treat the patient with the first therapeutic gas, the valve **12** is switched in such a way that the first therapeutic gas is carried from the gas tank **1** all the way to the patient (arrow). For purging purposes, the

valve **12** is switched in such a way that the tank **1** is switched off. Then the purging of the entire line **L2** and of the line **L1** all the way to the patient is initiated.

Figure 4 shows another embodiment whereby here, in comparison to Figure 3, the valve **14** is additionally provided near the patient connection, said valve having a line **16** leading towards the outside. By means of this valve **14**, the line **16** leading to the outside can be purged. Once again, the valve **6** with the optional second line to the patient for the second therapeutic gas from the tank **3** is drawn with a broken line.

Figure 5 shows another embodiment, whereby here no pressurized-gas source is employed for the other gas, but rather, the gas connection of the building or clinic itself, particularly for compressed air, is used. Thus, line **L2** consists of a connection to the compressed-air system of the clinic. For the therapeutic treatment of the patient, the valve **12** is switched to communicate between the gas tank **1** and the valve **6**. For purging purposes, the valve **12** is switched in such a way that the path to the gas tank **1** is closed. Compressed air from line **L2** can then flow through the entire system, thus clearing line **L1** all the way to the patient.

Figure 6 shows another embodiment similar to the embodiment in Figure 5. The difference here is a valve **14** which is located near the patient and by means of which a line **16** leading to the outside can be opened. The compressed air from line **L2** can be passed through the entire system all the way to valve **14** shortly before the patient connection, thus removing harmful gas components from the line **L1**.

Figure 7 shows another embodiment of the invention. The part of the first gas line **L1** that leads from the gas reservoir tank **1** containing the therapeutic gas to the patient (lower arrow) is the same as in Figure 1. The new aspect here is that an evacuation line **LS** is provided which comprises an evacuation line valve **8** and an evacuation element **10**. This can be, for instance, a vacuum pump or

else the vacuum connection at the hospital. If the patient is to be treated with the therapeutic gas after a treatment pause or prior to a new treatment, then, according to the invention, line **L1** can be freed of gas residues by opening valve **8** and putting the vacuum pump **10** into operation. The vacuum pump **10** then evacuates the contaminated parts of the system. Once the evacuation line valve **8** is closed, the normal treatment modality can be resumed by opening valve **6**.

Figure 8 shows another embodiment in which there is valve **12** near the gas tank **1** and there is a valve **14** near the patient. Once again, either only valve **12** can be employed or only valve **14**, or else both valves. When the valves **12** and **14** are closed, **L1** can be evacuated. Optionally, and thus drawn with a broken line, there can also be one or two lines **16** running from the outside to the valves **12** and **16** [*sic*]. During evacuation by means of the vacuum pump **10**, opening the valve **12** causes an air current from the atmosphere to be drawn in and this air current can then enter the gas circulation system, for example, through the valve **12** or the valve **14**. Thus, the line **L1** is not only evacuated but also purged with atmospheric air. When one of the two valves **12** or **14** is closed, only the corresponding line **16** draws in air from the outside or from the patient device. When both valves are closed, the line **L1** is evacuated.

Figure 9 shows another embodiment wherein the evacuation line **LS** is arranged at a different place. It is not located on the patient side of valve **6**, but rather on the other side. In addition, the valve **12** is provided here, which allows the gas circulation system **L1** to be shut off directly before the therapeutic gas tank **1**, thus allowing an even larger area of the line **L1** to be evacuated.

In Figure 10, in addition to what is depicted in Figure 9, the valve **14** is provided on the patient side, whereby here, it is optionally possible to provide an evacuation line **16** (hence drawn with a broken line). Then, during the evacuation operation, air can again enter line **L1** via the evacuation line **16** and the valve **14**. By the same token, the valve **12** can be provided with an evacuation line **16**, by means of which this part of the system can also be vented.

Figure 11 shows another embodiment of the invention whereby the evacuation line **LS** is connected to **L1** via a 3/2-way valve **14**. Another valve **12** serves to separate the gas tank **1**, thus allowing the purging of the line **L1** in its entirety. A dedicated evacuation device or vacuum pump is not provided here but instead, the evacuation line **LS** is connected to the hospital's own negative-pressure network.

Figure 12 shows a similar device except that the evacuation line connection **LS** is now directly near the gas tank **1** at the shut-off valve **12**. In this manner as well, the line **L1** can be cleared almost completely of detrimental gas components.

Figure 13 corresponds essentially to Figure 1. However, Figure 13 additionally shows an aerosol atomizer **18** that can deliver one or more therapeutically effective substances to line **L1**. This atomizer can likewise be purged with purging gas from gas tank **3**.

Such an aerosol atomizer **18** can also be employed, for example, in the embodiments shown in Figures 2, 5 or 6. In Figure 2, it is then preferably positioned before valve **16**, whereby "before" means that the aerosol atomizer **18** is located upstream from the valve **16**. In Figure 5, it is preferably arranged before the patient, in Figure 6 preferably between the valves **6** and **14**.

The embodiment shown in Figure 14 corresponds essentially to the embodiment in Figure 7. However, here an aerosol atomizer **18** is additionally provided which can deliver one or more therapeutically effective substances to line **L1**. This aerosol atomizer **18** likewise can be evacuated via the line **LS**.

Such an aerosol atomizer **18** can also be employed in the embodiments shown in Figures 8, 9 and 10. In Figure 8, it would preferably be arranged before the valve **14**, in Figure 9 preferably before the patient and in Figure 10 again before the valve **14**.